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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/052,771

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John A. Schillinger

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05/05/2006

Robert E Hanson  
FULBRIGHT & JAWORSKI LLP  
Suite 2400  
600 Congress Avenue  
Austin, TX 78701

EXAMINER

PARA, ANNETTE H

ART UNIT

PAPER NUMBER

1661

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/052,771

Applicant(s)

SCHILLINGER ET AL.

Examiner

Annette H. Para

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1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on February 21, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 13, 25, 33, 35, 39, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 25, 33, 35, 39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### **Status of the claims**

Claims 1-10, 13 are rejected. Claims 11, 12, 14-24, 26-32, 34, 36-38, 40, 41, and 44-49 are cancelled. Claims 25, 33, 35, 39, 42 and 43 are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Claim Objection**

The objection of the specification is withdrawn in view of applicant's amendment.

### **Status of Claim Rejections 35USC § 112**

In the previous Office action, dated 21 February 2006, claims 1, 2, 4-10 and 13 were rejected under 35 U.S.C. 112 first paragraph for lack of written description and scope of enablement.

The rejections of claims 1, 2, 4-10 and 13 are hereby withdrawn in view of Applicant's amendment to the claims inserting the limitation transgene.

In the previous Office action, dated 21 February 2006, claim 13 was rejected under 35 U.S.C. 112 second paragraph.

The rejection of claim 13 is hereby withdrawn in view of Applicant's argument, stating that the recitation "commercially acceptable grain yield" is defined in the paragraph 0034 of the specification.

### **Claim Rejections - 35 USC § 103**

Claims 1, 2, 4-10, and 13 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Padgett et al. (Crop Science 35:1451-1461. 1995) in view of Russell et al. (EPO 0430511A1) and further in view of Hacker et al. (U.S. Patent No. 5,599,769 1997).

Applicants' arguments filed on February 21, 2006 have been fully considered but they are not persuasive. Applicants argue that the prior art was devoid of a reasonable expectation of

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obtaining the claimed invention as of the filing date. And that absolutely no basis has been provided for concluding why one of skill in the art would have expected that transgenes conferring tolerance to both glyphosate and glufosinate could be expressed in a single soybean plant as of the filing date. (applicant's response page 7)

This is not found persuasive. As early as 1983 Jeff Schell and Marc Van Montagu (Ti plasmids as experimental gene vectors for plants. *Advances in gene Technology: Molecular Genetics of Plants and Animals. Miami Winter Symposia Vol. 20:191-209*) had produced tobacco plants that were resistant to kanamycin and to methotrexate. At the time of the claimed invention one of skill in the art would have been able to perform gene stacking and obtain soybean plants containing transgenes conferring tolerance to both glyphosate and glufosinate. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Hacker et al. (column 4, 1-19) explain :

For example, using the active substance combinations according to the invention, a herbicidal action is achieved which exceeds what would have been expected as an additive action of the individual components. Such increased effects permit the dosage rates of the individual active substances to be reduced substantially.

While the dosage rates are comparable, the weed-grass weed spectrum controlled is much broader by virtue of the synergistic effects. At the same time, properties, which are of the utmost importance in practical uses, are considerably improved in the case of most combinations. These include, for example, the speed of action, the long-term action, the flexibility upon use, etc. This permits comprehensive, rapid, sustained and economical control of weeds and grass weeds. Such properties are therefore economically progressive because they offer considerable advantages to the user in practical weed control by allowing him to control weeds more economically or more rapidly or in a more sustained manner, therefore obtaining higher yields in a stand of crop plants.

The combined teaching of the references of Padgett et al. in view of Russel et al. and further in view of Hacker et al. would have suggested the applicants to stack transgenes conferring both glyphosate and glufosinate resistance in soybean plants.

Applicants then argue that Hacker et al. reference established non-obviousness of the claimed invention. Using emphasis from Hacker et al. patent applicants then state that the

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activity of the combination of glyphosate and glufosinate is not additive and is in fact unpredictable (applicant's response page 8, last paragraph). This is not found persuasive. The statement of Hacker et al. (Column 1, lines 33-36) clearly shows that when applied in combination the active substance is much more efficient than when applied individually. This combination of active substance **stops dramatically the growth of plants** that are susceptible to the herbicides i.e. weeds. Hacker et al. teach that by using multiple herbicides control a much broader kind of weeds. Having crops comprising genes conferring resistance to both glyphosate and glufosinate allow to apply herbicide combination and thus to obtain a better control of weeds. In the previous office action examiner has shown that one of skill in the art would have been motivated to develop soybean plants comprising genes conferring resistance to at least glyphosate and glufosinate knowing that weed control is much broader when herbicide are used in combination than when they used individually. The combination of glyphosate and glufosinate is synergic hence; this combination achieves an effect of which each is individually incapable.

Applicant argues that because the combination of glyphosate and glufosinate is not additive and is unpredictable obtaining tolerance to both herbicides is also not additive and is unpredictable (response page 8).

This is not found persuasive because first, Applicant is comparing two unrelated things, a plant is reaction to the application of herbicides is not the same thing as a plant expressing two different genes. However, if the two were the same, it would provide an even stronger motivation to combine Padgett and Russell as one would expect very good resistance to the herbicides.

Applicant argues that the cited art relates to tolerance to either herbicide individually showing non obviousness. This is not found persuasive, because if the art showed tolerance to both herbicides in the same plant the claims would be rejected under 35 USC 102. Applicant's arguments are not the standard for non-obviousness.

Applicants then cite the Byrum declaration. Byrum's declaration filed on June 1, 2004 has been fully considered but it is not persuasive.

Byrum states that soybean plants do not naturally exhibit herbicide tolerance and that the effect of transgene expression is unpredictable (declaration page 3). This is not found

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persuasive. Nontransgenic resistance to the herbicide glyphosate has been observed in soybean plants and many plants have been produced that are resistant to glyphosate or glufosinate herbicides. Then Byrum declares that the expression of an herbicide resistance transgene creates a "metabolic drag". This is not found persuasive. Applicant has not cited any art showing that transforming a plant with EPSPS or PAT would create a metabolic drag. To make his point Byrum then cites several references. This not found persuasive. None of the references refer to transgenic plants, they are drawn to classical breeding and are all drawn to crossing plants with multi genes traits; crossing plants with two single gene traits is straight forward. Additionally the reference from Wilcox et al. shows that it is possible to cross soybean plants in order to transfer two traits that are each the result of numerous genes into the same plant. Also, crossing is not required to produce the instant plants, as transformation would suffice.

Examiner has presented "substantial evidence", showing that the stacking of genes conferring resistance to both glyphosate and glufosinate in soy bean plants was obvious at the time of the filing date of the claimed invention.

Applicant seems to be implying that expression of more than one transgene in a plant has never been done before. However it is done all the time. Plants are routinely transformed with constructs that express both selectable marker and the gene of interest. Expressing two genes in plants is routine, and one of skill in the art would not expect that both could not be expressed.

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### Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.

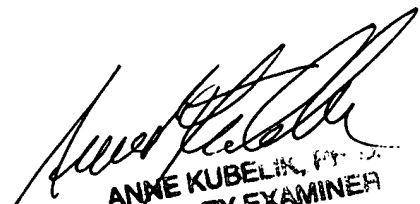
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about PAIR system, see <http://pair-direct.uspto.gov> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Annette H Para

April 20, 2006



ANNE KUBELIK, Ph.D.  
PRIMARY EXAMINER